## REMARKS

Applicants gratefully acknowledge the withdrawal of the previous 35 USC § 112 rejections. Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested.

### Status of the claims

Claims 3-5 and 11-24 are pending. Claims 3, 5, 11, 13-14, 18 and 20-21 are amended. Claims 3, 11 and 21 are amended for clarity and to correct claim dependency. Base claim 5 is amended to remove the percent weight limitation of component (d). Support is found throughout the substitute specification as originally filed, *inter alia*, on page 3, line 22, through page 4, line 6; and page 5, lines 14-27. Claims 13-14, 18 and 20 are amended for clarity. Support is found throughout the substitute specification as originally filed. Claims 1-2 and 6-10 were previously canceled. Claims 4, 12 and 22 are canceled in the present action. No new claims are added.

No new matter has been added.

### Summary of the Invention as Claimed

As currently amended, one aspect of the claimed invention is drawn to a fatty acid ester mixture of pentaerythritol, wherein the fatty acid is a C6-C22 fatty acid or fatty acid mixture, containing less than 0.3% by weight of esters containing C17 fatty acid acyl groups, and has a melting point of at least 30ºC, with (a) about 12-19% by weight monoesters, (b) about 25-35% diesters, (c) about 30-40% triesters, **and (d) tetraesters**, wherein the fatty acid ester mixture is **incorporated** as a wax component in cosmetic and/or pharmaceutical compositions (claims 3, 5, 21 and 23-24). In one embodiment of the invention as now claimed, the fatty acid esters **comprise** unbranched fatty acids (claims 21 and 24).

Another aspect of the invention as now claimed is drawn to a cosmetic and/or pharmaceutical composition comprising the above wax ester mixture (claims 11, 13-20).

**Rejections under 35 U.S.C. § 103(a)**

Previously pending claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Lindner (US 4,332,702) in view of Sakurai, et al. (US 4,113,635; "Sakurai"), in view of Memita et al. (WO 2002/22548, using US 6,939,980 as English translation; "Memita"), and further in view of Andrulis Jr. (US 5,654,312; "Andrulis). Applicants respectfully traverse the rejection.

In the present action, applicants have amended claim 3 to depend from claim 5, thereby mooting the Examiner's rejection. See discussion of claim 5, *vide infra*.

Previously pending claims 4 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lindner in view of Sakurai, in view of Memita, further in view of Andrulis. Applicants respectfully traverse the rejection.

Applicants have elected to cancel claims 4 and 22, thereby mooting the Examiner's rejection.

Previously pending claims 5 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sakurai in view of Memita and Andrulis, and further in view of Knothe, et al. (American Chemical Society monograph, 1997; "Knothe"). Applicants respectfully traverse the rejection.

Sakurai discloses rust-proof lubricant compositions for coating metals, comprising mono-, di- and tri- partial esters of pentaerythritol and fatty acids having more than 6 carbon atoms; melting points are stated to be in the range of 30-60°C (col. 1, lines 20-25). Example 3 discloses a fatty acid pentaerythritol ester mixture that is 20% monoester, 30% diester, 40% triester, and 10% tetraester, whereas applicants' claim 5 as presently amended discloses about 12-19% monoester, about 25-35% diester, about 30-40% triester, and the presence of tetraesters. As noted by the Examiner, Sakurai fails to disclose explicitly that the fatty acid is a **mixture** of fatty acids, and that the wax mixture is useful in cosmetic and/or pharmaceutical compositions. In order to cure these deficiencies in Sakurai, the Examiner joined Memita, Andrulis and Knothe.

Memita discloses a general **process** for producing an ester, comprising reacting an alcohol or polyol with a C5-C30 carboxylic acid to obtain a crude esterified product, adding 5-100 parts of a hydrocarbon solvent per 100 parts of crude ester, and neutralizing with an aqueous alkali solution. The polyol can be pentaerythritol. However, the described esters are **fully esterified tetraesters** as clearly disclosed in Memita's Examples. The pentaerythritol esters disclosed in Examples 1, 2 and 24-26, as well as their corresponding comparative examples, are all prepared with a reaction stoichiometry of >4:1 fatty acid:pentaerythritol, and the product esters are all characterized by low hydroxyl values, which demonstrates that the free OH content of the products is low (i.e. the product esters must be **tetraesters**). Thus, the products of Examples 1 and 2 have hydroxyl values of 0.8 mg KOH/g and 1.5 mg KOH/g, respectively. Specifically, the compounds of Example 2 and Comparative Example 2, cited by the Examiner, were prepared with a 4.125:1 ratio of (total stearic plus palmitic) acid:pentaerythritol, and both products have hydroxyl values of 1.5 mg KOH/g. As such, the compounds cited by the Examiner, of mp 67.7°C and 63.4°C are **tetraesters.** Nowhere in Memita is there disclosure of a **mixture of partial esters of pentaerythritol**, as presently claimed by applicants. Memita discloses that his **fully esterified** compounds are used in a wide range of fields, including cosmetics and pharmaceutical preparations. There is no specific disclosure in Memita regarding the utility of **mixtures of partial esters of pentaerythritol** in cosmetic and/or pharmaceutical compositions.

Andrulis discloses methods of treatment of inflammatory and autoimmune dermatoses, comprising topical administration of thalidomide in combination with other dermatological agents. The dermally applicable formulations may include "partial fatty acid esters of multivalent alcohols, such as ethylene glycol monostearate, glycerol monostearate, pentaerythritol monostearate..." (col. 11, lines 32-34). Thus, pentaerythritol **mono**stearate is specifically mentioned, but there is no disclosure of **mixtures** of partial fatty acid pentaerythritol esters, nor the specific benefits of such mixtures of partial fatty acid esters of pentaerythritol as disclosed and presently claimed by applicants.

In Example 3 of Sakurai, the partial esters were produced from beef tallow. Knothe discloses the fatty acid composition of beef tallow as containing a mixture of fatty acids.

Thus, the combination of cited art fails to lead one skilled in the art at the time of the invention, to applicant's pentaerythritol fatty acid ester **mixture**, incorporated as a wax component in a cosmetic and/or pharmaceutical composition.

Therefore, for at least these reasons, the claims as presently amended are patentably unobvious over the cited art.

Previously pending claims 11 and 14-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Barth et al. (US 2,441,555; "Barth"), in view of Memita, in view of Plough, Inc. (EP 0179416; "Plough"), and further in view of Bauer et al. (WO 2003/028690; using US 2004/0258721 as English translation; "Bauer"). Applicants respectfully traverse the rejection.

Barth discloses a process for preparing **tetraesters** of pentaerythritol with fatty acids containing 10 or more carbon atoms. Thus, an initially prepared monoester is further reacted with a different acid or anhydride (e.g. acetic anhydride) to form the fully esterified **tetraesters**. These product tetraesters are listed in Table I, together with their physical properties and starting materials. The melting point of 36-38°C quoted by the Examiner is for the **tetraester,** pentaerythritol triacetate monostearate (Table 1, first entry). Further, the physical data reported are for the full **tetraesters** and are therefore unrelated to applicants **partial ester** mixtures.

Barth also fails to teach pentaerythritol ester mixtures containing monoester, diesters and triester in various ratios. His synthesis method clearly discloses methods or preparing **monoesters** with fatty acids of 10 or more carbons, which is followed by reaction with acetic acid to form the full **tetraesters** comprising 3 acetate groups. This is in stark contrast to applicant's complex mixture of esters having acyl groups of varying carbon content, as well as mono-, di-, tri-, and tetra-ester species. Both Barth's intermediate monoesters as well as his ultimate product tetraesters comprising one fatty acid acyl group and three acetate groups, are outside the scope of applicants' partial

ester mixture. In particular, applicants' claims do not encompass a C2 (acetate) acyl group. Further, there is no indication that a product as divergent as Barth's, versus applicants' product, would have any utility whatsoever in the cosmetic and/or pharmaceutical arts, based on Barth's disclosure.

The Examiner stated that "claim 11, as interpreted by the Examiner is not limited to a partial ester" (Office Action, page 22, number 38). However, as presently amended by applicants, claim 11 is no longer a product-by-process claim, but is a composition claim depending from claim 5. Further, the esters of Barth are reported to be useful in the plastics and coatings fields as modifiers, which are clearly unrelated to cosmetic and/or pharmaceutical utility as presently claimed by applicants. Thus, the disclosed utility of Barth would not teach, motivate or suggest to one skilled in the art that his compositions would have any reasonable probability of success as components of cosmetic or pharmaceutical compositions.

The Examiner noted that the differences between Barth and applicants' claimed processes include the lack in Barth of specific disclosure regarding (1) utility in cosmetic and/or pharmaceutical compositions, (2) wax components, non-ionic surfactants and oil components, (3) the wax component being fatty alcohols and partial glycerides, and (4) mixtures of mono-, di-, tri- and tetra-esters in specific ratios. In order to cure the substantial deficiencies noted in Barth, the Examiner joined Memita, Plough, and Bauer.

Memita is discussed above.

Plough and Bauer both are drawn to **fully esterified tetraesters**, and are therefore unrelated to applicants' **partial ester** mixtures as presently claimed. Examples 93, 94 and 96 of Bauer (p. 46), disclose pentaerythritol **tetra**isostearate. Also, Plough discloses "pentaerythritol **tetra** (C20 – C24) aliphatic hydrocarbon carboxylates" (page 2, bottom paragraph). In contrast, applicants' claims are now drawn to fatty acid **partial ester mixtures**, with specific ranges of mono-, di-, and tri-esters, and the presence of tetra-esters. Therefore Plough and Bauer are unrelated to applicants' presently amended claims, and cannot cure the substantial deficiencies of Barth disclosed above.

Further, for the sake of argument, even if the pentaerythritol tetraesters of Plough were relevant art, which they are not as discussed above, applicants' previously

submitted declaration disclosed comparative testing of a composition of the present invention versus a composition comprising the preferred tetraester as specifically taught by Plough, pentaerythritol tetrabehenate (Plough, page 3, top paragraph; all Examples). As clearly demonstrated by the comparative data in the previously submitted declaration, the ester mixture of the present invention provides a useful and stable cosmetic emulsion, whereas the comparison **tetraester** of Plough does not (emulsion separated). Thus the ester mixtures and compositions of applicants are distinguished over the cosmetic cited art, and are patentably unobvious.

Thus, the combination of cited art fails to lead one skilled in the art at the time of the invention, to applicant's fatty acid ester **mixture** of pentaerythritol, incorporated as a wax component in a cosmetic and/or pharmaceutical composition.

Therefore, for at least these reasons, applicants' cosmetic and/or pharmaceutical composition claims, as presently amended, define unobvious subject matter over the cited art.

Previously pending claims 11-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lindner, in view of Sakurai, in view of Memita, and further in view of Andrulis. Applicants respectfully traverse the rejection.

Rejected claim 11 is discussed above. The Examiner is reminded that claim 11 is currently amended to depend from claim 5. Claim 12 is canceled in the present action, thereby mooting the rejection in regard to that claim.

Lindner discloses partial esters of pentaerythritol useful as internal lubricating agents for lowering the viscosity of polyvinyl chloride resins, as well as hydrogen chloride scavengers. The fatty acid portion of the partial pentaerythritol esters comprises 0-10% C14, 0-5% C15, 30-60% C16, 0-5% C17, and 30-60% C18. The partial esters are 25-45% monoester, 40-60% diester, and 15-30% triester, **being substantially free of the tetraester**. As acknowledged by the Examiner, Lindner's esters do not have applicants' claimed melting point of at least 30°C; a fatty acid ester mixture of pentaerythritol wherein the fatty acids comprise C6-C22 species; and a cosmetic and/or pharmaceutical composition. Therefore, the Examiner joined Sakurai, Memita and Andrulis.

Sakurai, Memita and Andrulis are discussed above. However, as discussed above, these references are unable to cure the substantial deficiencies of Lindner.

However, applicants' base claim 5, as presently amended, **requires the presence of tetraesters**. Thus, the combination of cited art fails to lead one skilled in the art at the time of the invention, to applicant's pentaerythritol fatty acid ester **mixture**, incorporated as a wax component in a cosmetic and/or pharmaceutical composition.

Therefore, for at least these reasons, applicants' cosmetic and/or pharmaceutical composition claims, as presently amended, define unobvious subject matter over the cited art.

Previously pending claims 21 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sakurai in view of Kirk-Othmer (Wiley-Interscience, 1993, vol. 10, 4th ed., page 267; "Kirk-Othmer"), in view of Memita, and further in view of Andrulis. Applicants respectfully traverse the rejection.

Sakurai, Memita and Andrulis are discussed above.

Kirk-Othmer was joined for the composition of coconut oil fatty acids.

As presently amended, claim 21 depends from claim 5. See the discussion of rejected claim 5, above.

In conclusion, the limitations of applicants' claims 21 and 24 as presently amended are not taught by the combination of cited references. Therefore applicants' claims as presently amended are novel and patently unobvious over the cited art.

**Conclusion**

In summary, in view of the above claim amendments and remarks, applicants believe that the pending claims as amended are in condition for allowance. The Examiner is respectfully requested to enter the amendments, reconsider, withdraw the rejections and allow the claims.

If any additional fees are required in support of this application, authorization is granted to charge our Deposit Account No. 50-1943.

Respectfully submitted,

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